

1.0 Definition of the Procedure

Mechanical cardiopulmonary support goes by many names under the general heading of extracorporeal life support. When the heart/lung machine is used in venoarterial mode to provide total support of heart and lung function to facilitate cardiac operations, the technique is commonly called cardiopulmonary bypass (CPB). When used with extrathoracic cannulation for respiratory support it is called extracorporeal membrane oxygenation (ECMO), extracorporeal lung assist (ECLA), and extracorporeal CO₂ removal (ECCOR). The abbreviations ECMO and ECLS are used synonymously to mean prolonged extracorporeal circulation with mechanical devices.

ECMO exists in two varieties: veno-arterial (VA), and veno-venous (VV). The VA ECMO partially supports cardiac output, and the VV ECMO does not support circulation. ECLS management, indications and results are quite different for cardiac and respiratory support and also different for neonates, pediatrics and adult patients. In general, ECLS is indicated in acute severe reversible respiratory or cardiac failure, when the risk of dying from the primary disease despite optimal treatment is high.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at <http://www.dhhs.state.nc.us/dma/prov.htm>.

3.0 When the Procedure is Covered

The N.C. Medicaid program covers extracorporeal membrane oxygenation (ECMO), extracorporeal life support (ECLS) as follows:

3.1 ECMO in neonates who meet **all** of the following criteria:

1. Any of the following diagnoses:
 - a. hyaline membrane
 - b. congenital diaphragmatic hernia
 - c. respiratory distress syndrome
 - d. cardiac anomaly
 - e. persistent fetal circulation
 - f. meconium aspiration
2. gestational age of at least 34 weeks
3. birth weight of 2000 grams or more
4. no more than 10 days old

3.2 ECMO/ECLS in children and adults meeting any of the following criteria:

1. as a short term (hours to a few days) bridge to heart transplant, once transplant has been approved
2. Acute Respiratory Distress Syndrome (ARDS)
3. reversible causes of cardiac failure, myocarditis, and cardiomyopathy
4. pulmonary contusion
5. non-necrotizing bacterial or viral pneumonia

3.3 Individual Evaluation

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

4.0 When the Procedure is Not Covered

The N.C. Medicaid program does not cover extracorporeal membrane oxygenation (ECMO), extracorporeal life support (ECLS) for any of the following:

4.1 ECMO in Neonates

1. Any severe diagnosis, which decreases the probability of survival (i.e. severe & irreversible brain damage)
2. Intracerebral hemorrhage
3. Multiple congenital abnormalities
4. Age more than 10 days
5. Contraindication to systemic anticoagulation

4.2 ECMO/ECLS in Children and Adults

1. 60 years or greater
2. Necrotizing pneumonia
3. Multiple organ failure
4. Metastatic disease
5. Major CNS injury
6. More than 10 days on mechanical ventilation prior to start of ECMO/ECLS
7. Non-reversible respiratory or cardiac failure

8. Contraindication to systemic anticoagulation
9. History of or active substance abuse - must have documentation of substance abuse program completion plus six months of negative sequential random drug screens
Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
10. Psychosocial history that would limit the ability to comply with medical care pre and post transplant
11. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

Prior approval for procedures provided to **neonatal recipients who are not candidates or potential candidates for transplants** must be requested through DMA's fiscal agent.

Prior approval for procedures provided to **recipients who are candidates or potential candidates for transplants** must be requested from DMA.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized for extracorporeal membrane oxygenation (ECMO), extracorporeal life support (ECLS).

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of the procedure.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A

Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Physicians bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered under the extracorporeal membrane oxygenation (ECMO) include:

- 36822
- 33960
- 33961

D. Providers must bill their usual and customary charges.